

**Remarks/Arguments**

The Office Action stated that Claims 1 to 20 are pending, and that Claims 1, 11 to 14 and 19 have been rejected.

The Office Action stated that Claims 8 to 10 are drawn to non-elected inventions.

The Office Action stated that Claims 2 to 7, 15 to 18 and 20 have been objected to.

The Office Action stated that objected to Claims 2 to 7, 15 to 18 and 20 would be allowable if rewritten in independent form including all of the limitations of the base (independent) claim and any intervening claims. Applicants thank the Examiner for indicating that such dependent claims would be allowable if rewritten as specified. Claim 2 has been put into independent form by including all of the limitations, etc., of Claim 1 – applicants request the allowance of amended Claim 2 and all of the claims directly and indirectly dependent thereon. Claim 15 has been put into independent form by including all of the limitations, etc., of Claim 1 – applicants request the allowance of amended Claim 15. Applicants

The Office Action stated: that the election of group I, Claims 1 to 7 and 11 to 15 (also 16 to 20) with traverse in the Paper filed June 1, 2009, is hereby acknowledged; that, however, no reason is given for the traversal; and that, therefore, the restriction is deemed proper and made final.

The Office Action stated that the following is a quotation of 35 U.S.C. 103(a) which forms the basis for the obviousness rejection set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in Section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negated by the manner in which the invention was made.

The Section 103(a) rejection is defective and fails, for among other reasons, because there is no factual resolution in the record of the level of ordinary skill in the pertinent art. Without such missing factual resolution in the record, the Patent Office can not know anything about one ordinarily skilled in the art, can not make any valid obviousness rejection under Section 103(a), and can not make or establish any valid *prima facie* showing of obvious. The Patent Office has the burden of proof and the Patent Office has not carried its burden of proof.

The Examination Guidelines Update: Developments In The Obviouness Inquiry After KSR v. Telefax, Federal Register, Vol. 75, No. 169, Sept. 1, 2010, pp. 53643-53660, states:

“...the factual inquiries announced in *Graham v. John Deere*, ...(...; level of ordinary skill in the art; ...), remain the foundation of any determination of obviousness.” [Emphasis supplied] [Page 53644]

“.... the Graham inquiries and the associated reasoning are crucial to a proper obviousness determination, .... It remains Office Policy that appropriate factual findings are required in order to apply the enumerated rationales properly. If a rejection has been made that omits one of the required findings, and in response to the rejection a practitioner or inventor points out the omission, Office personnel must either withdraw the rejection, or repeat the rejection including all required factual findings.” [Emphasis supplied] [Pages 53644 and 53645]

The required factual resolution (finding) of the level of ordinary skill in the pertinent art is missing (omitted) in the Office Action (as the last amendment pointed out was also the case with the prior Office Action). The withdrawal of the obviousness rejection is requested. If the obviousness rejection is repeated it is requested that it include the required finding of the level of the ordinary skill in the art. It is also requested that in the latter case that the new Office Action be nonfinal as it is basically a new rejection (since the prior rejection was

defective and faulty). Applicants have the right to traverse the required finding and to submit arguments, evidence, reasons, law, etc., to show that the new supplied required finding is in error, etc.

Claims 1, 11 to 14 and 19 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Sakaraba et al., Chem. Pharm. Bull., Vol 43(5), (1995), pages 748 to 753, in view of (i) Staszak et al., EP 0 457 559 A2, (ii) Okeda et al., EP 0 955 303 A2, and (iii) Antognazza et al., U.S.Patent No. 5,907,045; individually. Applicants traverse this rejection.

The Office Action unsuccessfully attempted to establish a prima facie showing of obviousness but failed, for along with other reasons, it did not factually resolve the level of ordinary skill in the pertinent art. The lack of this mandatory factual resolution means that the obviousness rejection fails and the attempt to establish a prima facie showing of obviousness also fails. Applicants request allowance of the claimed invention.

Section 2143. A, of the MPEP, (Rev. 6, Sept. 2007), involving prima facie obviousness rejections, states, for example:

“To reject a claim based on this rationale, Office personnel must resolve the *Graham* factual inquiries.” [Emphasis supplied]

The Patent Office has not factually resolved in the record the level of ordinary skill in the pertinent art, hence the Patent Office has not made a showing of prima facie obviousness.

The Office Action stated that applicants claim a process of making carboxylic acid salts of compounds of formulae Ia and/or Ib, comprising asymmetric hydrogenation of a carboxylic acid salt with aminoketones of formula II, in the presence of a catalyst comprising a transition metal complex of a diphosphine ligand. (This is not a correct statement of applicants' Claim 1. The Patent Office has not proven that the rejected claims are obvious [under Section 103(a)] over such combinations of rejection references. The Patent Office

has not even proven that such three secondary rejection references can each separately be combined with the primary reference in the quest for applicants' claimed invention. The Patent Office has not proven that it has established a *prima facie* showing of obviousness of applicants' claimed invention.

The Office Action stated:

Determination of the scope and content of the prior art (MPEP 2141.01)

The Office Action stated that Sakaraba et al. teaches a process of making HCl acid salt of compounds of formulae Ia and/or Ib comprising asymmetric hydrogenation of an HCl acid salt with aminoketones of formula II, in the presence of a catalyst comprising a transition metal complex of a disphosphine ligand. Applicants traverse this statement because it is an unjustified attempt to generify the narrow and specific disclosure of Sakaraba et al. Furthermore, it is an incorrect statement of the disclosure of Sakaraba et al.

The Office Action stated see reaction schemes in Tables 1 and 2, and pages 748 and 749. Such disclosure is not relevant because Sakaraba et al. discloses a different process that is not even suggestive of applicants' claimed process.

The Office Action stated that also, in Claims 11, 13 and 14, applicants claim specific ligands. Their use in the applicants' new process means that the combinations of applied references are not relevant,

Also, this is a defective statement of the state and content of the prior art. This statement does not even discuss the state and content of the three secondary rejection references, let along the references supplied by the applicants. The term "prior art" in this category of the requirements to establish a factual showing in the record of *prima facie* obviousness does not merely mean the applied rejection references. The Patent Office also needs to consider all of the prior art located, developed, etc., by the prior art search(es) made by the Patent Office in the examination of this application.

The Office Action stated:

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The Office Action stated that the difference between the instant invention and that of the prior art is that applicants use of a salt of carboxylic acid instead of a salt of HCl to prepare the corresponding salt of compounds of formula I. Applicants traverse this statement. The Patent Office has again fallen into the error of including only the primary rejection reference in “the prior art” required by this category. Not only that, the incorrect description above of the narrow disclosure of the primary rejection reference means that this statement is part of an unjustified attempt to generify the primary rejection references’ narrow disclosure.

The Office Action stated that, also, the ligands in Claims 11, 13 and 14 are different from the ligand of the prior art. The claimed process is a new process.

The Office Action stated:

Finding of prima facie obviousness—rational and motivation (MPEP 2142.2413)

The Office Action stated that, however, Staszak et al. teaches a similar process using HCl salts with aminoketones, wherein R<sup>1</sup> is the thienyl ring. Applicants traverse this statement as the Patent Office has continued to incorrectly generify the narrow disclosure of Sakaraba et al. The attempted combination of the primary rejection reference and Staszak et al. (and the other two combination rejections) fails because, for example, the Patent Office does not know what references, if any, one ordinarily skilled in the art would use.

The Office Action stated that the “prior art” also teaches that salts of other acids, such as, carboxylic acids (e.g. oxalate), are applicable. What “prior art”?

The Office Action stated see page 5, lines 2 to 7. Such disclosure is of no import under Section 103(a) because, for example, the Patent Office has not factually resolved in the record the level of ordinary skill in the pertinent art – such factual resolution is required.

The Office Action stated that Okeda et al. (pages 1 to 24, particularly, page 2, lines 11 to 15) and Antognazza et al. (col. 1 to 8) teach the ligands in Claims 11, 13 and 14 are useful for asymmetric hydrogenations reactions. Such unjustified attempt to generify the narrow and limited disclosure such two secondary rejection references shows that the combination rejections are in error. The attempted obviousness rejection and the attempted showing of *prima facie* obviousness fail.

The Office Action stated that using a catalytic amount of the catalyst is inherent in Claim 1. This statement is of no import in a rejection under Section 103(a).

The Office Action stated that, therefore, it is not a limitation since the amount is not specific with support in the specification. Applicants traverse this statement of speculationas being in error in fact and law. The Patent Office has not proven otherwise. If it is inherent, then it supported. Furthermore, one ordinarily skilled in the art can readily and with minimal testing obtain the limits of “a catalytic amount”

The Office Action stated that, therefore, the instant invention is *prima facie* obvious from the teachings of the prior arts. Applicants traverse this statement and have shown above that no showing of *prima facie* obviousness has been made by the Patent Office.

The Office Action stated that one of ordinary skill in the art of asymmetric hydrogenation of aminoketones would have known to use a salt of carboxylic acid and/or change the ligand in the process by Sakaraba et al. at the time this invention was made. Applicants traverse this statement. The Patent Office knows nothing about one ordinarily skilled in the art because the Patent Office has not resolved the level of ordinary skill in the art. The Office Action stated that motivation is from the teachings of Staszak et al. that salts of carboxylic acids are applicable and from the various ligands disclosed by Okeda et al. and Antognazza et al. This statement is clearly in error because the Patent Office does not know what would motivate, or anything else concerning one ordinarily skilled in the art.

The Office Action stated that, according to the court of *Orthopedic Equipment Co., Inc. v. All Orthopedic Appliances, Inc.*, Appeal Nos. 83 to 513, 83 to 525 Slip op. at 13 (Fed. Cir. May 16, 1983, 217 USPQ 1281, 1281), factors that may be considered in determining level of ordinary skill in the art include: (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field. The above factors are ones that might be used in determining (resolving) the level of ordinary skill in the pertinent art, however the Patent Office still has not resolved (using such factors or in some other way) the level of ordinary skill in the pertinent art. The Patent Office has not done anything with such factors except to recite such factors - that is not factual resolution in the record of the level of ordinary skill in the art.

The Office Action stated that the court went further stating that:

Although educational level of the inventor may be [a] factor to consider in determining level of ordinary skill in art, it is not conclusive; other factors that may be relevant in ascertaining level of ordinary skill in art include various prior art approaches employed, types of problems encountered in art, rapidity with which innovations are made, sophistication of technology involved, and educational background of those actively working in field.

The Patent Office has not factually resolved the level of ordinary skill in the art so the Section 103(a) rejection still fails and is defective.

The Office Action stated that the court in *Environmental Designs, Ltd. et al. v. Union Oil Company of California et al.*, 218 USPQ 865 (Fed. Cir. 1983), stated:

Not all such factors may be present in every case, and one or more of these or other factors may predominate in a particular case. The important consideration lies in the

need to adhere to the statute, i.e., to hold that an invention would or would not have been obvious, as a whole, when it was made, to a person of "ordinary skill in the art" – not to the judge, or to a layman, or to those skilled in remote arts, or to geniuses in the art at hand.

The Supreme Court and Patent Office policy require factual resolution in the record of the level of ordinary skill in the art, and if such resolution is absent (as is the case here) the obviousness rejection fails on that ground alone (as is the case here).

The Office Action stated that at the time the instant invention was made, workers were engaged in asymmetrical hydrogenation of an HCl acid salt with aminoketones of formula II, in the presence of a catalyst comprising a transition metal complex of a disphosphine ligand. This is a failed and unjustified attempt to generify the limited and narrow disclosure of the applied prior art. The Patent Office is requested to support such assertion with a reference or declaration, or to drop the assertion.

The Office Action stated that it was not known if there was problem with salts of HCl acid – this alone shows that this obvious rejection is incorrect and only based on mere forbidden hindsight.

The Office Action stated that, but, other workers such as Staszak et al. suggest a salt of carboxylic acid is applicable. Applicants traverse this statement. The Patent Office is requested to recite where Staszak et al. supports the Patent Office's assertion and explain how such recited portions of Staszak et al. supports the Patent Office's assertion.

The Office Action stated that Okeda et al. and Antognazza et al. teach various catalysts comprising a transition metal complex of a disphosphine ligand. (Such description of such references is so generic, without justification, to be worthless in trying to make a factual showing of *prima facie* obviousness.) Such disclosure is of little value under Section 103(a) because the Patent Office has not established that one ordinarily skilled in the art

would be directed by such disclosure to the fact that there were problems with HCl salts and how to solve such problems.

The Office Action stated that, therefore, it would have been obvious to try a salt of carboxylic acid or change the ligand in the process of Sakaraba et al. by any worker engaged in asymmetric hydrogenation of an HCl acid salt with aminoketones of formula II, including the inventor, at the time the invention was made. Applicants traverse this statement. This statement is of no value under Section 103(a) because it does not say to whom it would be obvious to try such, and the Patent Office cannot assert that it would have been obvious to one ordinarily skilled in the art (because, for example, the Patent Office has not resolved the level of ordinary skill in the art). Also, the Patent Office does not know when the invention was made.

The Office Action stated that the choice of a salt of carboxylic acid or ligand represents a finite and predictable solution. Applicants traverse this statement. The Patent Office is requested to prove in the record that such choice (a) is finite and (b) is predictable. Prove this statement or withdraw it is what applicants request.

The Office Action stated that it has a reasonable expectation of success because Staszak et al., Okeda et al., and Antognazza et al. made such predictions. Applicants traverse this statement. First, applicants request that the Patent Office prove in the record that such rejection references made such predictions (let alone in reference to or applicable to applicants' specific claimed invention). Second, such assertion is meaningless because it cannot apply to one ordinarily skilled in the art since the Patent Office has not resolved the level of ordinary skill in the art.

The Office Action stated that, alternatively, applicants have substituted one known element (a salt of carboxylic acid/ligand) for another (a salt of HCl acid/ligand) to obtain a result predicted by Staszak et al., Okeda et al., and Antognazza et al. Applicants traverse

this statement. The Patent Office has not shown that such three references disclose or even suggest the problem solved by applicants' claimed invention. The three references are not pertinent because they have not been shown to be ones that would be chosen by one ordinarily skilled in the art. Also it has not been shown that the three references predicted any result. Section 103(a) requires facts, not speculation.

The Office Action stated that the instant invention is a modification of the process by Sakaraba et al., grounded in common sense, because Staszak et al., Okeda et al., and Antognazza et al. suggested it could be done. This statement is incorrect and of no value under Section 103(a) because, among other things, such references do not even suggest the problem solved by applicants' claimed invention, and it not oriented to one ordinarily skilled in the art.

The Office Action stated: "When a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result." *United States v. Adams*, 383 U.S. 49, 50 to 51 (1966), cited in *KSR Int. Co. v. Teleflex Inc.*, 550 U.S. ---, 82 USPQ2d 1385 (2007). KSR requires the factual resolution in the record of the level of ordinary skill in the art or else no obviousness determination can be made – therefore, the quotation is of no meaning in the present case. Determination of the level of ordinary skill in the art is mandatory – if it is missing, any obviousness rejection fails.

The Office Action stated: "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR, supra*. Again, this quotation is meaningless in the present case because there has not been any factual resolution in the record of the level of ordinary skill in the art.

The Office Action stated that, alternatively, the instantly claimed process of using carboxylic acid salts and ligands in asymmetric hydrogenations is not applicants' invention.

Applicants traverse this statement. This statement says "the instantly claimed invention" [Emphasis supplied] - this is not an anticipation rejection, so this statement is clearly in error. The claimed invention is applicants' invention.

The Office Action stated that they were in the public domain prior to the time the instant invention was made. Applicants' claimed invention has not been shown by the Patent Office to be in the public domain at any time.

The Office Action stated that applicants have done nothing more than combine separate but well-known "prior art[s]" inventions from Sakaraba et al. and Staszak et al., according to known methods to yield predictable results. Applicants traverse this statement. The Office Action has not shown that the cited references are even combinable, or that predictable results are involved, or that the problem solved by applicants was known to the authors or the art. This obviousness rejection does not even get off the ground because the Patent Office has not even factually resolved in the record the level of ordinary skill in the art (which is mandatory).

The Office Action stated that applicants' result is predictable by the prior arts. Applicants again contest this statement and request that that Examiner prove such assertion in the record. The Patent Office cannot prove that applicants' result is predictable to one ordinarily skilled in the art – the level of ordinary skill in the art has not been resolved in the record.

The Office Action stated that while the combination may perform a useful function it did no more than what they would have done separately, and cited *In re Anderson*, 396 U.S. 57, 163 USPQ 673 (1969) cited in *KSR Int. Co. v. Teleflex Inc.*, 550 U.S. ---, 82 USPQ2d 1385 (2007). This statement is of no meaning in this case because the Patent Office has not factually determined in the record the level of ordinary skill in the art.

The Office Action stated: that, when a patent simply arranges old elements with each performing the same function it had been known to perform and yields predictable result, the combination is obvious; and cited *In re Sakraida*, 425 US 273, 189 USPQ 449 (1976) cited in *KSR*, *supra*. Applicants traverse this statement. The cited case is not relevant because KSR has said that the level of ordinary skill in the art has to be determined or a Section 103(a) rejection fails. The Patent Office has not proven that "predictable result" is present.

The Office Action stated: that a patent for such combination "obviously withdraws what is already known into the field of its monopoly."; and cited *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 187 USPQ 303 (1950), cited in *KSR*, *supra*. Applicants traverses this statement as it presumes something that has not been proven to be.

The Office Action has not proven that applicants' claimed invention is obvious under Section 103(a), and has not established a *prima facie* showing of obviousness. The Patent Office has not carried its burden of proof.

Applicants request withdrawal of this rejection.

The Office Action stated that applicants' arguments filed February 2, 2010 have been fully considered but they are not persuasive. The Patent Office's statement

The Office Action states that applicants' contends the Office Action fails to resolve the level of ordinary skill in the art. Applicants' assertion is correct in fact, law, Supreme Court decisions, Patent Office policy, the 9/1/2010 Patent examination guidelines update, etc.

The Office Action stated that this is not persuasive because applicants' argument is a conclusive statement, not supported with evidence, legal and or factual analysis of who is an ordinary skill in the art and how such analysis relates to applicants' position. Applicants'

assertion is a fact – nowhere in the present Office Action and the prior Office Action has the Patent Office factually resolved (or attempted to do such) in the record the level of ordinary skill in the art. Applicants' prior amendment (for example, pages 8 to 12, plus 20 attached supportive pages from Supreme Court decisions and the MPEP) supporting set out analysis, legal support, etc., on the issue.

The Office Action stated that Claims 2 to 7, 15 to 18, and 20 are objected to as being dependent upon a rejected base claim, but would be allowable of rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 1 has been placed in independent form and been amended to include the limitations, etc., of Claim 1. The claims directly or indirectly dependent upon amended Claim 2 should also be allowed. As to Claim 20, applicants intend to further review the rejection references.

Withdrawal of this objection is requested.

Check in the amount of \$444.00 for the two extra independent claims is enclosed.

Reconsideration, reexamination and allowance of the claims is requested.

Respectfully submitted,

November 15, 2010

Date

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<b>CERTIFICATE OF MAILING</b> I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on <u>November 15, 2010</u> <u>Virgil H. Marsh</u> FISHER, CHRISTEN & SABOL 1156 15th Street, N.W., Suite 603 Washington, D.C. 20005
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